K110709

MAY 19 2011

ARK Care™ 510(k) Summary

Submitter:	ARKRAY Factory USA, Inc. 5182 W. 76th Street Minneapolis, MN 55439
Contact Person:	Tyler Foutch Regulatory Affairs Project Manager ARKRAY Factory USA, Inc. 5182 W. 76th Street Minneapolis, MN 55439 Phone: 952-646-3171 Fax: 952-646-3110 tfoutcht@ARKRAYusa.com
Date Prepared:	March 8, 2010
Trade Name:	ARKRAY ARK Care Diabetes Management System™
Classification:	Glucose test system, 21 CFR 862.1345; Class II Calculator/data processing module for clinical use, 21 CFR 862.2100; Class I
Product Codes:	CGA, NBW, JQP.
Predicate Device:	MCT Diabetes™ (K073699).
Device Description:	**ARK Care** system serves as an interface between the software in personal glucose monitoring devices and a general purpose health management database to assist in the review, analysis and evaluation of blood glucose test results. The secure system is compliant with HIPAA and HITECH standards. **ARK Care** is designed for home use and professional healthcare settings. It is an accessory device to most manufactured model home-use blood glucose monitors, including glucose monitoring devices by ARKRAY, Roche, Bayer, LifeScan, and Abbott. The list of supported devices is located at *www.arkcare.net.* The purpose of the electronic diabetes management system is to help users and healthcare teams manage blood glucose information to better regulate diabetes treatments and control blood glucose for better health outcomes. The **ARK Care** system holds a convenience function, as the user can upload blood glucose data from a variety of currently marketed blood glucose monitors into one location for viewing. After the user transmits and stores blood glucose data to the secure database, the **ARK Care** system allows family members and/or healthcare professionals to view and monitor the user's data and reports. Family and healthcare team members must receive permission from the primary user and create a password protected login before viewing data. **ARK Care** provides a safe communication portal for the user, family, and healthcare team to send email-like messages to the protected profiles and comment on specific data

	entries, improving patient care and disease management. The user and approved healthcare team members can view the blood glucose data in different formats such as logbooks, charts, and graphs. The data can be viewed through selected time intervals and these intervals can be compared over time to track disease management. The subject can also enter and track other health-related information such as body weight, blood pressure, lab values, and exercise activities. Groups of profiles can be queried for bulk reporting on data related to tracking and trending of outcomes, supporting diabetes disease management in individuals and in managed care organizations.
Intended Use:	ARKRAY ARK Care Diabetes Management System™ is intended for use in home and clinical settings via the internet to assist people with diabetes and their healthcare professionals in uploading, storing, analyzing, and communicating about historical blood glucose test results and other biological statistics to support diabetes management.
Functional and Safety Testing:	A full array of in-house testing was done consistent with relevant FDA guidance's for blood glucose monitoring systems. Testing included validation of the systems hardware (USB data transfer cable) and software as well as consumer studies that demonstrated the systems ability to be easily operated by in-home users.
Conclusion:	Labeling, validation testing results and consumer studies results support the Indications for Use and the claim of substantial equivalence to the predicate (K073699).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 19 2011

Arkray Factory Usa, Inc.
c/o Tyler Foutch
Project Manager Regulatory Affairs
5182 West 76th St.,
Minneapolis, MN 55439

Re: k110709
Trade/Device Name: ARK Care™ Diabetes Management System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, CGA, JQP
Dated: March 11, 2011
Received: March 14,2011

Dear: Mr. Foutch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k110709

Device Name: ARK CARE™ DIABETES MANAGEMENT SYSTEM

Indication For Use:

The ARKRAY Diabetes Management Software is an optional accessory for use with compatible blood glucose meters, such as ARKRAY Glucocard Vital Blood Glucose Meter with data management capabilities. The ARKRAY Diabetes Management Software transfers data from the meter's memory into a secured sever for enhanced data management. ARKRAY ARK Care™ Diabetes Management System is intended for use in home and clinical settings via the internet to assist people with diabetes and their healthcare professionals in uploading, storing, analyzing, and communicating about historical blood glucose test results and other biological statistics to support diabetes management.

Prescription Use _____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use __X__. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) __k110709____